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ADDING TRIAMCINOLONE TO VISCOSUPPLEMENTATION: ONE YEAR OUTCOME OF RANDOMIZED TRIAL

G.C. Campos, M.U. Rezende, R. Fruchi, T. Pasqualin, M.I. Hissadomi. *IOT – FMUSP, São Paulo, Brazil*

Purpose: This is an extended follow up of a randomised controlled trial to evaluate if the addition of triamcinolone to viscosupplementation could alter one-year pain and function of viscosupplementation alone.
Methods: We prospectively enrolled 104 patients with knee osteoarthritis and randomized them to receive either a single intraarticular injection (6 mL) of hylan GF-20 (Group viscosupplementation [Group VS]), or a single intraarticular injection of hylan GF-20 (6 mL) and 1 mL (20 mg) of triamcinolone hexacetonide (Group VS+T). VAS, WOMACTM, and Lequesne questionnaires were completed at baseline, at weeks 1, 4, 12, 24 and at one year.
Results: At week 1 the WOMAC and VAS scores were lower in Group VS+T, compared with Group VS. There was no difference regarding the adverse effects. At weeks 4, 12, 24 and one year there were no differences within the groups. At one year only Group VS+T still showed a difference from baseline for VAS.
Conclusions: The addition of triamcinolone hexacetonide improves first-week symptom and functional scores of viscosupplementation and does not alter its adverse effects. There might be benefits for the one year pain results.

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LONG-TERM EFFECT OF A FLEXIBLE MINIMALIST SHOE ON ALGO-FUNCTIONAL, ANALGESIC MEDICATION INTAKE AND GAIT KINEMATIC IN ELDERLY WOMEN WITH KNEE OSTEOARTHRITIS

A. Matias, F. Trombini-Souza, M. Yokota, I. Pereira, C. Schainberg, R. Fuller, I.C. Sacco. *Univ. of Sao Paulo, Sao Paulo, Brazil*

Purpose: To evaluate the therapeutic effect of a minimalist and inexpensive footwear on pain, function, gait kinematics and paracetamol intake in elderly women with knee OA.
Methods: A randomized, parallel and controlled clinical trial, with blind assessor was carried out. Fifty-six elderly women with knee OA graded 2 or 3 (Kellgren and Lawrence) were randomly allocated into the intervention group (IG, n = 28) or the control group (CG, n = 28) and assessed at baseline (T0), after three (T3) and after six months of intervention (T6). The IG patients should wear the minimalist shoes (Moleca®) for at least 6-hours daily. Moleca® shoe (Calçados Beira Rio S.A., Novo Hamburgo, RS, Brazil) is a women's double canvas flexible flat walking shoe without heels, with a 5-mm anti-slip rubber sole. The CG could not wear these shoes or any other similar, as well as be under physical therapy or acupuncture treatment for the knee OA throughout these 6-months. Paracetamol intake (500 milligrams) for every 6 hour was allowed for both groups only in extreme pain situation. The outcomes of the study were: Lequesne algo-functional score, paracetamol intake, and lower limb kinematics while walking. The time effects (T0, T3 and T6), group (IG and CG) and interaction (time vs. group) were tested by two-way casewise ANOVA.
Results: The IG wore the Moleca® shoe for an average monthly of 7h40 a day, achieving improvement of 35% in Lequesne algo-functional score at T3 ($p < 0.001$; large within-group effect size: 1.07) and 43% at T6 ($p < 0.001$; large within-group effect size: 1.31). In CG, there was an improvement of 23% at T3 ($p < 0.001$; moderate within-group effect size: 0.71) and 16% at T6 ($p < 0.001$; moderate within-group effect size: 0.45). From T3 to T6, the CG got worse in the Lequesne algo-functional score in 8.9%, while the IG showed an improvement throughout the 6-months. The CG significantly increased the rescue medication intake throughout the trial, which possibly resulted in their algo-functional improvement. The IG, on the other hand, showed just a slightly increase in the paracetamol intake at the end of the 1st, 2nd and 3rd months. However, at 4th, 5th and 6th months, the paracetamol intake was again similar to the baseline status. From the 2nd to 6th month, this practice was significantly higher in CG compared to IG. Although the IG patients have achieved a higher improvement in algo-functional aspect of the disease, and a reduction in rescue medication intake, there was no interaction effect for: knee early flexion ($p = 0.293$), knee final flexion ($p = 0.742$), knee extension ($p = 0.337$), and sagittal range of the knee ($p = 0.417$).
Conclusion: The results suggests that the usage of Moleca® shoe can be considered as a conservative treatment of knee OA to improve the algo-functional aspects and to reduce the analgesic medication intake, keeping unchanged the kinematics of the knee during gait.

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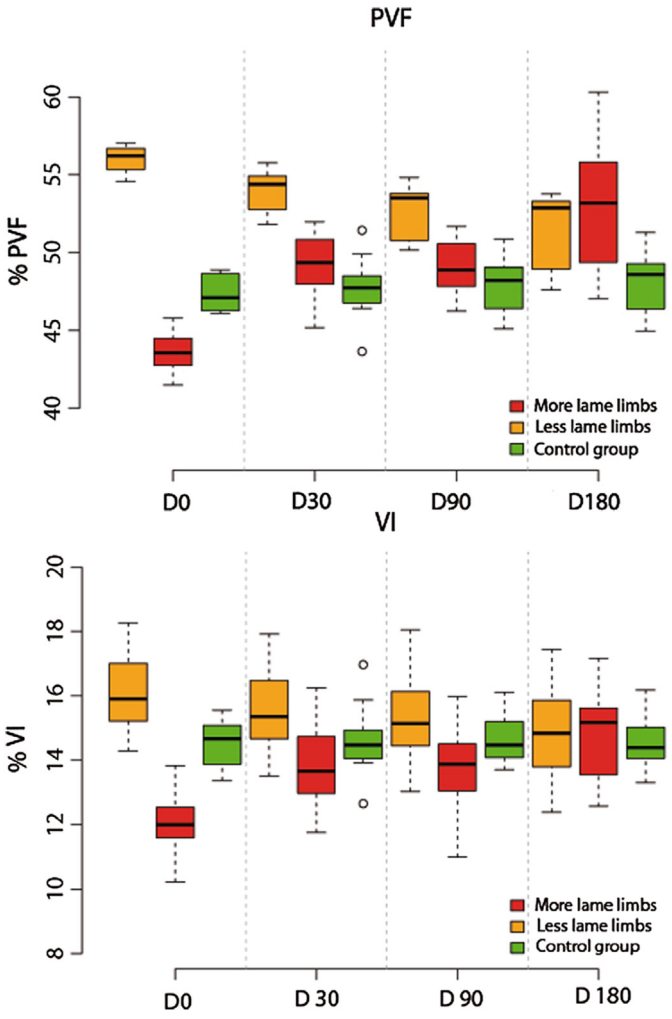
FORCE PLATFORM ANALYSIS OF THE EFFECT OF INTRARTICULAR INJECTION OF AUTOLOGOUS ADIPOSE-DERIVED MESENCHYMAL STEM CELLS ASSOCIATED TO PRGF IN OSTEOARTHRITIC DOGS

M. Rubio Zaragoza †·‡, B. Cuervo Serrato †·‡, J.M. Carrillo Poveda †·‡, J.J. Sopena Juncosa †·‡, R. Cugat Bertomeu §·‡, M. Garcia Balletbo §·‡, M. Morales Fariña ‖, J.M. Vilar Guereño ‖. † *Univ. CEU Cardenal Herrera, Alfara del Patirarca, Spain;* ‡ *Garcia Cugat Fndn. CEU-UCH Chair of Med. and Regenerative Surgery, Valencia, Spain;* § *Artroscopia GC, Barcelona, Spain;* ‖ *Univ. Las Palmas de Gran Canaria, Las Palmas de Gran Canaria, Spain*

Purpose: Adipose-derived mesenchymal stem cell (aMSC) therapy in regenerative medicine is a rapidly growing area of research and is currently also being used to treat osteoarthritis (OA). Force platform analysis has been consistently used to verify the efficacy of different therapeutic strategies for the treatment of OA in dogs, but never with aMSC. Recent investigations have shown that growth factors contained in platelet-rich plasma (PRGF) act as vehicles and even potentiators of the effect of aMSCs. The purpose of this study was to use force platform kinetic analysis to evaluate the effect of a single intraarticular injection of aMSC in 8 dogs with OA of hip joints by measuring peak vertical force (PVF) and vertical impulse (VI), which represent maximal weight bearing and distribution of forces through time, respectively.
Methods: Eight adult client-owned Canarian Presa dogs (5 males, 3 females) with OA were infiltrated with aMSC and PRGF. Dog owners were informed and granted a signed consent for the whole procedure. Stem cell extraction and inoculation phases were performed under general anesthesia (sevoflurane). The adipose tissue (inguinal region) was processed using the Dog Stem® (Fat-Stem) protocol. The number of mesenchymal stem cells was over 30 million, certified with a laboratory certificate for the quality of the cells and received in two 2 ml tubes with 15 million per tube. Once the aMSC were received they were infiltrated with the PRGF-Endoret® that was prepared in that moment (centrifuged during 8 minutes at 460 G and activated with 5% of its volume with 10% calcium chloride). The resultant 4 ml solution was injected aseptically into the hip joints through conventional artrocenthesis sites. Gait analysis was performed using a single platform mounted in the center of, and level with, a 7-m runway covered by a rubber mat. The mat weight was discarded setting to "0 force" with the tare button after the platform was covered. Dogs were leash guided at walk over the force platform by the same handler. Walk velocity was measured by use of a motion sensor (Pasco, California, USA) positioned 1 m apart from the platform. Five valid trials, at a sampling frequency of 250 Hz, were obtained for each dog. A member of the research team evaluated the trial to confirm which limb touched the center of the force platform. The platform was interfaced with a dedicated computer using DataStudio®. Data were recorded from both affected limbs at day 0, 30, 90, and 180 post-treatment; the obtained PVF and VI values were normalized relative to body weight (%) to characterize the possible improvement of lameness during treatment with aMSCs. Data were analyzed with a linear mixed effects model for a blocked design with repeated measures. The time and the lame-sound of the dog were considered as fixed effects factors, while the dog was a random effects factor. Significance of the differences in PVF and VI between periods of observation was tested by means of analysis of variance of these models, with a post-hoc Tukey's test. For assessing the relationships between supporting force in the more-lame and the less-lame limbs and also between vertical impulses in the two limbs, a regression model with random effects of dog on slope and intercept was used. Significance level was set at $P \leq 0.05$ in all tests.
Results: Eight lame dogs with severe hip OA and a control group of 5 sound dogs were used for this study. Results were statistically analyzed to detect a significant increase in peak vertical force (PVF) and vertical impulse (VI) in treated dogs. Mean values of PVF and VI were significantly improved after treatment of the OA groups, reaching 53.02% and 14.84% of body weight, respectively, at day 180, compared with only 43.56% and 12.16% at day 0.
Conclusions: This study objectively demonstrated that intraarticular aMSC therapy resulted in reduced lameness due to OA.



reconstruction. Synaflexor standardized flexion weightbearing X-rays are obtained on patients pre-operatively. Patient reported outcomes are being collected at 6 time points up to 6 months post-ACL reconstruction with a focus on function and symptoms (IKDC, KOOS) activity level (Marx-score), quality of life (KOOS-QOL, SF36) and pain (VAS, KOOS-pain, Catastrophizing scale, CSQ).

Results: Only data from one cohort are available to date. Our practice performs ~ 400 ACL reconstructions annually. Pre-study data showed capture of 85.7% of all ACL injuries occurring in Fayette County: 66% of patients were seen within 30 days after ACL injury; 37% were seen by a Surgeon but 73% were seen by a Surgeon or PCP within 1 week of injury; 30% were seen within 4 days of injury. A total of 10 patients were eligible for enrollment in a 4 month time period. After this pre-study data changes were made to the study design including development of an "early warning system" through physician extenders in high schools and placement of additional physician extenders in the clinics to help with enrollment. These changes allowed for enrollment of 30 patients in a 7 month time period, a 220% increase in enrollment numbers from the pre-study period. 10–20% of all patients with ACL tears fulfill the inclusion criteria. Screen failures occur at a rate of 25–30% due to either accompanying injuries (n = 6) or patient refusal (n = 4). No patient withdrew from the study. One patient refused the second knee joint aspiration. No patient was lost to follow-up. No problems were encountered regarding the data collection, specimen storage or patient follow-up.

Conclusions: ACL patients can be recruited to a PTOA prevention trial within 4 (+ 4) days after ACL injury if typical patient referral patterns are changed. Even for a highly productive ACL practice it is imperative to involve PCPs, Surgeons and outreach physician providers as stake holders into the study. Early knee joint aspirations are well tolerated and can be performed consecutively without patient withdrawals. Patients report subjectively less pain after the aspirations. Few patients refuse enrollment. Strict inclusion criteria result in a low number of eligible patients (10–20% only). A careful pre-study analysis of referral patterns, patient capture and environment is critical to perform randomized clinical trials in this patient population.

Ages (yrs)	Mechanism of Injury	Prior Knee Surgery		Contra lateral Knee Status
		Ipsilateral	Contralateral	
12–33	Playing a sport	No	No	Normal

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MOON-AAA GCP CLINICAL TRIAL: EARLY LESSONS FROM AN EARLY INTERVENTIONAL TRIAL IN PATIENTS WITHIN 1 WEEK AFTER ACL TEAR

C. Lattermann †, M. Proffitt †, V.B. Kraus ‡, K.P. Spindler §. † *Univ. of Kentucky, Lexington, KY, United States;* ‡ *Duke Univ., Durham, NC, United States;* § *Cleveland Clinic Fndn., Cleveland, OH, United States*

Posttraumatic Osteoarthritis (PTOA) often results from knee ligament injuries such as to the anterior cruciate ligament (ACL). Patients with ACL injuries are a unique population the initiation event for the development of PTOA is often known. Enrolment of these patients and the prospective collection of "early" information on this population is challenging as the majority in the US will not be seen by a specialist until several weeks after injury. We here describe the early lessons learned from the "Multicenter Orthopaedic Outcome Network Early-Anti-inflammatory Treatment in Patients with Acute ACL Tear and Painful Effusions" (MOON-AAA) clinical trial. This is the first US-based multicenter, randomized, good clinical practices (GCP) interventional clinical trial recording biomarker profiles, standardized X-rays as well as patient reported outcomes (PRO's) in isolated ACL tears seen within 4 days after ACL injury.

Methods: This is a GCP multicenter clinical trial enrolling patients with primary isolated ACL tears within 4 days after injury. Inclusion criteria follow the MOON -protocol (Table 1). All patients undergo aspiration of the post-injury effusion within 4 days and 10 days post-injury. Patients receive an injection with 40 mg Kenalog within 4 days, 10 days, both time points or not at all (saline injection control). Permutated block randomization into one of these four groups is done at the time point of the first aspiration. Blinding of patients and investigators is maintained throughout the study. Serum, synovial fluid and urine collection is performed at the first and second aspiration as well as at the time of ACL

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TUG AND FTSST IN KNEE OA PATIENTS SUBMITTED TO AN EDUCATIONAL PROGRAM (PARQVE – PROJECT ARTHRITIS RECOVERING QUALITY OF LIFE BY MEANS OF EDUCATION)

F.E. Farias, C.A. Silva, C.H. Cernigoy, M.U. Rezende, O.P. Camargo. *Faculdade Med. USP, Sao Paulo, Brazil*

Purpose: Evaluate the improvement of function and balance in patients with OA undergoing an educational program of a day with multidisciplinary.

Methods: Two hundred and two patients with knee OA were submitted to two tests: Timed and Go (TUG) and Five Times Sit to Stand Test (FTSST) at enrollment and one year after an educational program (PARQVE). Patients were divided in four groups and received take home written and audiovisual material on OA. Groups 1 to 3 had two days of lectures with orthopedic surgeons, physical therapists, psychologists, occupational therapists, nutritionist, physical educators, social workers. Group 4 received the written and audio material. All patients were oriented to exercise at least three times a week. Each group was subdivided in A (received bimonthly telephone calls) and B (no telephone calls).

Results: All groups improved in TUG irrespective of the group they were in with no significant difference between them ($p = 0.097$). When considering only groups 1 to 4, (irrespective of telephone calls) FTSST showed a difference between groups ($p = 0.037$), however ANOVA could not show what group was different. But when comparing groups that had classes (1+2+3) with the group that just received the educational material (4), TUG showed trends of difference $p = 0.066$ and FTSST improved significantly in the class group $p = 0.012$.

Conclusion: Patients improve function and balance with education and attention.